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| APPLICATION NO.                                                      | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|----------------------------------------------------------------------|-------------|----------------------|---------------------|------------------|
| 10/644,288                                                           | 08/20/2003  | Paul Diamond         | PT100-3             | 5798             |
| 53255                                                                | 7590        | 07/22/2008           | EXAMINER            |                  |
| PAUL DIAMOND<br>1605 JOHN STREET,<br>SUITE 102<br>FORT LEE, NJ 07024 |             |                      | POPA, ILEANA        |                  |
|                                                                      |             |                      | ART UNIT            | PAPER NUMBER     |
|                                                                      |             |                      | 1633                |                  |
|                                                                      |             |                      | MAIL DATE           | DELIVERY MODE    |
|                                                                      |             |                      | 07/22/2008          | PAPER            |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/644,288

**Applicant(s)**

DIAMOND, PAUL

**Examiner**

ILEANA POPA

**Art Unit**

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**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 17 March 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 17-20, 25, 27, 29, 30, 32 and 36-40 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 17-20, 25, 27, 29, 30, 32, and 36-40 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

1. Claims 22 and 24 have been cancelled. Claims 1-16, 21, 23, 26, 28, 31, and 33-35 have been withdrawn. Claims 17, 18, 25, and 29 have been amended.

Claims 17-20, 25, 27, 29, 30, 32, and 36-40 are under examination.

2. All rejection pertaining to claims 22 and 24 are moot because Applicant cancelled the claims in the reply filed on 03/17/2008.

The rejection of claims 18, 19, 29, 30, and 32 under 35 U.S.C. 101, as being directed to non-statutory subject matter, is withdrawn in response to Applicant's amendments to the claims filed on 03/17/2008.

The rejection of claims 18-20, 22, 24, 29, 30, 32, 36, and 40 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement is withdrawn in response to Applicant's amendments to the claims filed on 03/17/2008.

The rejection of claims 17-20, 25, 27, 29, 30, 32, and 36-40 under 35 U.S.C. 103(a) as being unpatentable over Oliver et al. (U.S. Patent No. 5,723,765, incorporated by reference in the instant specification), in view of Porter (Trends Genet, 1998, 14: 73-79) is withdrawn in response to Applicant's amendments to the claims filed on 03/17/2008.

### ***New Rejections***

#### ***Claim Rejections - 35 USC § 103***

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3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 17-20, 25, 27, 29, 30, 32, and 36-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oliver et al. (U.S. Patent No. 5,723,765, of record), in view of both Porter (Trends Genet, 1998, 14: 73-79, of record) and Angell et al. (EMBO J, 1997, 76: 3675-3684, Applicant's IDS).

Oliver et al. teach a method of making a genetically modified plant by regenerating a whole plant from a genetically plant cell, wherein the genetically modified plant cell comprises (i) DNA sequences having a pre-selected gene linked to a pre-selected constitutively active promoter, wherein the gene and the promoter are separated by a blocking sequence flanked on each side by specific excision sequences, (ii) a gene encoding a recombinase that recognizes the specific excision sequences linked to a repressible promoter, and (iii) a gene encoding the repressor protein specific for the repressible promoter; the expression of the repressor protein is controlled by an outside stimulus, wherein the application of the stimulus blocks the repression of the recombinase leading to the excision of the excisable blocking sequence (claims 17, 18, 20, 37, and 38) and brings the pre-selected gene under the control of the pre-selected promoter (claims 25, 27, 29, 32, 36, 39, and 40) (Abstract, column 1, lines 58-67, column 3, lines 1-67, column 4, lines 40-65, column 7, lines 7-20). Oliver et al. also teach that the blocking sequence may contain an herbicide resistance gene, i.e., the

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excisable element comprises an expression cassette with a pre-selected gene (claims 19 and 30) (column 5, lines 30-32). Oliver et al. do not teach causing RNA silencing against the mRNA encoding the repressor (claims 17, 18, 25, and 29). However, at the time the invention was made, the prior art taught silencing of pre-selected genes by introducing into cells a nucleic acid complementary to all or part of the pre-selected genes, wherein the complementary nucleic acid could be a RNA (see for example Porter, p. 78, columns 1 and 2). Because Oliver et al. and Porter teach methods of inactivating pre-selected genes, it would have been obvious to one of skill in the art, at the time the invention was made, to substitute one method for the other to achieve the predictable result of inactivating the desired gene. Although Oliver et al. and Porter teach causing RNA interference to excise the pre-selected DNA sequence from the plant cell genome, they do not specifically teach causing RNA interference to silence the repressor by providing a repressor having a sequence complementary to a strand of a viral double-stranded RNA and infecting the cell with the double-stranded RNA virus (claims 17, 18, 25, and 29). However, at the time the invention was made, such an approach was taught and used in the prior art. For example, Angell et al. teach using silencing of transgenes modified such as to include part of the replicating potato virus X (PVX) RNA and infecting the plant cell comprising the transgene with the unmodified PVX; Angell et al. also teach that silencing using viral double-stranded RNA is a more reproducible approach for inducing silencing in plants, as opposed to the other methods (p. 3679, column 1, last paragraph, p. 3680, column 1, p. 3682, column 2, last paragraph). Based on these teachings, it would have been obvious to one of skill in the

art, at the time the invention was made, to modify the method of Oliver et al. and Porter according to the teachings of Angell et al. to achieve the predictable result of obtaining reproducible inactivation of pre-selected genes in plant cells. Thus, the claimed invention was *prima facie* obvious at the time the invention was made.

### ***Conclusion***

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ILEANA POPA whose telephone number is (571)272-5546. The examiner can normally be reached on 9:00 am-5:30 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ileana Popa, PhD

/Joseph T. Woitach/  
Supervisory Patent Examiner, Art Unit 1633